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10/808,791

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FRA V2002/0026 US CIP

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10/05/2006

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EXAMINER

WARE, DEBORAH K

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/808,791

Applicant(s)

VISKOV ET AL.

Examiner

Deborah K. Ware

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-49 are presented for examination on the merits.

Foreign Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in France on September 23, 2002. It is noted, however, that applicant has not filed a certified copy of the France 02 11724 application as required by 35 U.S.C. 119(b) or none has been observed by the examiner in EDAN so it is considered to not be in the case Serial No. 10/665,872. A certified priority document is requested if none has been filed in case Serial No. 10/665,872.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 10/665,872. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the two sets of copending claims is scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims of instant case are drawn to method for analyzing heparins by depolymerizing heparin in a sample with heparinases, optionally reducing the sample, and assaying the sample by HPLC (High Performance Liquid Chromatography).

Copending claims are drawn to methods of quantifying a sample by by depolymerizing a sample with heparinases, and assaying the sample by HPLC (High Performance Liquid Chromatography).

The claims differ as noted above in terms of their scope of how the claims are drafted, however, the same steps are effectively employed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to employ the steps of the copending claims in a method of depolymerizing heparin in a sample as claimed herein. Expected successful results would have been obtained and one of skill would have been motivated to select heparinases for depolymerization based upon the teachings of the copending claims.

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The claims are prima facie obvious because each of the copending claims teaches the claimed features as set forth in the instant case.

Claims 1-49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-16 of copending Application No. 10/808,410 in view of US Patent No. 5744132 and US Patent No. 6617316. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the two sets of copending claims is scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims of instant case are drawn to method for analyzing heparins by depolymerizing heparin in a sample with heparinases, optionally reducing the sample, and assaying the sample by HPLC (High Performance Liquid Chromatography).

Copending claims are drawn to method of assaying a sample by depolymerizing a sample with heparinases, and assaying the sample using reverse chromatography.

US Pat No. '132 teaches reverse phase chromatography, see figure 11.

US Pat No. '316 teaches depolymerizing with heparinases and SAX chromatography, see column 2, lines 33-48 and column 3, line 27.

The claims differ as noted above in terms of their scope of how the claims are drafted, however, the same steps are effectively employed except reverse phase is used and not HPLC.

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It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to employ the steps of the copending claims in a method of depolymerizing heparin in a sample as claimed herein. Expected successful results would have been obtained by selecting the functional equivalent of reverse phase chromatography as disclosed by US Pat No. '132 and one of skill would have been motivated to select heparinases for depolymerization based upon the teachings of the copending claims and what is known in the art as taught by US Pat Nos. '316 and '132. The claims are prima facie obvious because each of the copending claims teaches the claimed features as set forth in the instant case.

Claims 1-49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-18 of copending Application No. 10/808,409. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the two sets of copending claims is scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims of instant case are drawn to method for analyzing heparins by depolymerizing heparin in a sample with heparinases, optionally reducing the sample, and assaying the sample by Chromoatography for the content of the sample.

Copending claims are drawn to methods of quantifying a sample by by depolymerizing a sample with heparinases, and assaying the sample by Chromoatography to determine glycoserine.

The claims differ as noted above in terms of their scope of how the claims are drafted, however, the same steps are effectively employed except there are particulars with respect to the chromatography employed and glycoserine is being analyzed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to employ the steps of the copending claims in a method of depolymerizing heparin in a sample to determine content as claimed herein. Expected successful results would have been obtained for analyzing the same sample for any desired component (i.e. glycoserine) using the similar method steps differing only in the scope of how the two sets of claims are claimed. One of skill would have been motivated to select heparinases for depolymerization and/or a treating step based upon the teachings of the copending claims. The claims are prima facie obvious because each of the copending claims teaches the claimed features as set forth in the instant case.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Mourier et al (US Patent No. 6,617,316), cited on enclosed PTO-1449 Form.

Claims are drawn to method for analyzing heparins comprising depolymerizing a sample with heparinases, optionally reducing the sample, and assaying by HPLC.

Mourier et al teach method for analyzing heparins comprising depolymerizing a sample with a mixture of heparinases, and assaying by HPLC, see column 2, lines 30-35 and line 48 and column 3, line 13 and lines 27-28.

The claims are identical to the cited disclosure and are, therefore, considered to be anticipated by the teachings therein as noted above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-4 and 6-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mourier et al (US Patent No. 6617316), discussed above in view of Debie (US Patent No. 5,389,618) both cited on enclosed PTO-1449 Form, Lopez (US Patent No. 4,981,955), Sasisekharan et al (US Patent No. 5,569,600), Petitou et al (US Patent No. 4,801,583) and Bergendal et al (US Patent No. 5,039,529), all of these cited on enclosed PTO-892 Form.

Claims are discussed above. Further, the oligosaccharides present are modified with a 1,6-anhydro bond.

Mourier et al teach method for analyzing heparins comprising depolymerizing a sample with heparinases, and assaying by HPLC, see column 2, lines 30-35 and line 48 and column 3, line 13 and lines 27-28. Further, the oligosaccharides present are

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modified with a 1,6-anhydro bond and the chromatography is anion exchange, see column 1, line line 27 and column 8, lines 1-15.

Debrie teaches enoxaparin and mobile phase chromatography region up to 206nm wherein phosphate salt buffer is used. Note column 6, lines 66-67 and column 7, line 1 and 30.

Lopez teaches reducing agent for depolymerized heparin, i.e. sodium borohydride (alkali metal salt of borohydride), note column 5, line 45.

Sasisekharan et al teach mixture of heparinases, including I, II and III, note column 4, lines 30-37.

Petitou et al teach also oligosaccharide comprising at least one 1,6-anhydro residue, note column 16, lines 3 and 26.

Bergendal et al teach acetylated sugars and detection of components, see column 2, lines 35-37 and see figure 1.

The claims differ from the teachings of Mourier et al in that a mixutre of enzymes, reducing agent: borohydride, enoxaparin, mobile phase and acetylated sugars are not specifically disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of Mourier et al, Debie, Lopez, Sasisekharan et al, Petitou et al and Bergendal et al in order to provide for an analyzing method for enoxaparin selecting a mixture of heparinases of I, II, III, for which to depolymerize and then reduce the depolymerizant with borohydride for detection of components such as acetylated sugars as all of these claimed features are disclosed by the secondary cited references. One of skill would have expected successful results for depolymerizing enoxaparin and to then reduce it by the disclosed agent is clearly taught. Further, to detect other components, such as acetylated sugars, upon applying mobile phase and HPLC chromatography for analyzing a sample containing heparin is clearly within the skill of an artisan. Further, to modify the oligosaccharides with 1,6-anhydro bond is clearly an obvious modification as it clearly prevalent and disclosed by Peitou et al to be an obvious and desirable bond for which to modify oligosaccharide components from a depolymerized sample as disclosed by Mourier et al. One of skill would have been motivated to perform the steps as claimed because they are clearly disclosed in the cited prior art for analyzing a heparin containing sample. Furthermore, depolymerization with a mixture of heparinases is clearly disclosed as well. In the absence of unexpected successful results the claims are rendered prima facie obvious over the cited prior art.

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All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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DEBORAH K. WARE

PATENT EXAMINER

Deborah K. Ware
September 30, 2006